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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,612	05/15/2006	Jason Gordon Beith	207195 (8830-318)	9867

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Gregory J Lavorgna
Drinker Biddle & Reath
One Logan Square
18th & Cherry Streets
Philadelphia, PA 19103-6996

EXAMINER

STROUD, JONATHAN R

ART UNIT	PAPER NUMBER
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3709

MAIL DATE	DELIVERY MODE
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08/10/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/524,612

Applicant(s)

BEITH, JASON GORDON

Examiner

Jonathan R. Stroud

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 16 and 17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-7 and 9-15 is/are rejected.
- 7) ☒ Claim(s) 2 and 8 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 2/16/2005.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☒ Other: Appendix I.

DETAILED ACTION

The following title is suggested: "Cardiac valve featuring a parabolic function."

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-3, 5, 7 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Martyn 6,375,679, published Mar. 27, 2000.
3. A cardiac valve prosthesis with a frame and flexible leaflets; the frame comprises an annular portion which, in use, is perpendicular to the blood flow [Fig. 3], the frame having first and second ends, one of the ends defining at least two scalloped edge portions separated and defined by posts [11, 12], each leaflet being attached to the frame along a scalloped edge portion and being movable between an open and a closed position, each of the leaflets having a blood inlet side, a blood outlet side and at least one free edge [Fig. 2, 7], in a first plane perpendicular to the blood flow axis the length of each leaflet in a circumferential direction (XY) between the posts at any position along the longitudinal axis (Z) of a post is defined by a parabolic function [col. 7

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II. 50-53, 60-68 ... "the leaflets form part of a parabaloid of revolution having its axis of revolution lying in a plane orthogonal to the direction of the blood flow"].

4. The formula $Y_z = \left(\frac{4R}{L_z^2} \right) x \cdot (L_z - x)$ defines a parabolic function with two free constants, R and L_z . Rearranging the terms, you can derive the formula $y = Ax + Bx^2 + C$, C being zero, and defining a standard parabolic function.

$$\text{Length} = \int_0^L \sqrt{1 + \left(\frac{dy}{dx} \right)^2} dx$$

The formula defines the arc length of a parabola as shown in appendix I. [Martyn teaches a flap defined by a parabolic profile as discussed above, col. 7, II. 50-53, 60-68]

5. Further, Martyn teaches a valve prosthesis comprising three leaflets [Fig. 2, 7], at least one leaflet is configured to increase the length of the free edge of the leaflet relative to the length of the leaflet in the XY direction [col. 1 II. 28-32; if the leaflets are "flexible" then the free edge will stretch and expand upon use, increasing the length of the free edge relative to the length of the leaflet], leaflet has first and second lateral edges each for attachment to a corresponding post, wherein the length of the leaflet in a circumferential direction (XY) between the lateral edges at any position along the lateral

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edge for attachment to the post is defined by a parabolic function [col. 7 ll. 50-53, 60-68]. Claim 8 is a substantial repetition of claim 2's limitations.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Martyn in view of Yang 2002/0138138 A1. Martyn teaches the heart valve as discussed above, but fails to teach the following claimed limitations taught by Yang: having the frame comprise a collapsible stent [para. [0011]]. It would have been obvious to one of ordinary skill in the art at the time of invention to modify Martyn in view of Yang, in order to enable a less traumatic delivery of the device in vivo, by decreasing the radial dimensions, and further securing the valve in place, as taught by Yang, [pars. [0005]-[0010]].

7. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Martyn in view of Moe 6,613,086. Martyn teaches the heart valve as discussed above, but fails to teach the following claimed limitations taught by Moe: the free edge of the leaflet configured so that the longitudinal direction of the free edge is parabolic with respect to the z axis [122, col. 5 ll. 48-62 ... "such shapes include parabolic cylinders 122 (i.e. a projection of an paraboloid out of an x-y plane along a z-axis)]. It would have been

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obvious to one of ordinary skill in the art at the time of invention to modify Martyn in view of Moe, in order to provide a shape that can be represented by analytic geometry, increasing the durability of the leaflet by moving the leaflet's point of maximum loaded stress along the attachment curve away from the location of stress risers, as taught by Moe [col. 2 ll. 19-35].

8. Claims 9, 10, 11, 12, and 13 are 35 U.S.C. 103(a) as being unpatentable over Martyn in view of Kolff 4,473,423. Martyn teaches the heart valve as discussed above, but fails to teach the following claimed limitations taught by Kolff: A method for manufacturing such a valve comprising engaging a mold and a frame, applying a coating and removing the mold [Claim 7, Col. 10: "(a) preparing a mold contoured to match, (b) positioning a ring member (frame), (c) vacuum forming a thermoplastic material over said mold (coating), (d) removing mold"]. It would have been obvious to one of ordinary skill in the art at the time of invention to modify Martyn in view of Kolff, in order to provide an artificial heart valve made of synthetic material that can be readily mass-produced, as taught by Kolff, [col. 1, ll. 60-68, col. 2 ll. 1-2].

9. Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martyn in view of G. Cacciola et al ("A stentless fibre-reinforced aortic valve prosthesis," Journal of Biomechanics, Volume 33, Issue 5, May 2000, Pages 521-530) as disclosed and claimed. Martyn teaches the heart valve with possible varying valve configurations as discussed above, but fails to teach the following claimed limitations taught by Cacciola: a method of stress-testing the heart valve to determine optimal design, as taught by Cacciola. It would have been obvious to one of ordinary skill in the

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art at the time of invention to modify Martyn in view of Cacciola, to analyze and optimize the design and reduce the stress concentrations in the valve, as taught by Cacciola

[Abstract].

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See works cited.

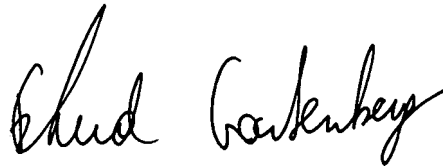
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan R. Stroud whose telephone number is 571-270-3070. The examiner can normally be reached on Monday through Friday, 7:30 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ehud Gartenberg can be reached on (571) 272-4828. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jonathan Stroud/

A handwritten signature in black ink, appearing to read "Ehud Gartenberg".

EHUD GARTENBERG
SUPERVISORY PATENT EXAMINER

8/6/07